1.0 Abstract

Title: Effectiveness and Safety of Adalimumab in Patients with Psoriatic Arthritis in Normal Medical Practice

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Keywords: Adalimumab, psoriatic arthritis, adverse events, effectiveness, disease activity

Rationale and Background: Psoriatic arthritis (PsA) has been estimated to affect up to 0.4% of adults and approximately 30% of psoriasis patients in Germany. Non-interventional observational studies supplement clinical trials by providing data on the real-world clinical activity of therapeutic agents such as adalimumab.

Research Question and Objectives: The research question explored in this study was whether the effectiveness and safety of adalimumab was maintained during long-term therapy of PsA patients in routine clinical practice in Germany.

Primary study objectives were:

- Effectiveness (as assessed by changes in Disease Activity Score-28 joints [DAS28], joint involvement, and psoriasis)
- Safety (as assessed by reports of drug-related adverse events [AEs])

Secondary objectives included changes in:

- Additional disease activity parameters, including dactylitis, enthesitis, nail psoriasis, and erythrocyte sedimentation rate
- Patient-reported outcomes, including global disease activity, fatigue, pain, and function
- Socioeconomic parameters , including impairment in daily activities, sick leave, and hospitalization
- Concomitant medication

Exploratory analyses included:

- Patient and disease parameters influencing changes in DAS28, function, or psoriasis at month 6

Study Design: Prospective, multicenter, observational (case-only) non-interventional

Setting: Routine clinical practice in Germany

Subjects and Study Size: Adult PsA patients: 4635 subjects in safety set and 3552 subjects in full analysis set (FAS; used for effectiveness analyses)

Variables and Data Sources:

Key variables: DAS28; expanded joint counts (78 for tender joints and 76 for swollen joints); body surface area (BSA) affected by psoriasis; target lesion score (TLS) for psoriasis; presence of dactlitis, enthesitis, and nail psoriasis; AEs; patient-reported assessments of function (Funktionsfragebogen Hannover [FFbH]), global disease activity, pain, and fatigue; socioeconomic outcomes (days of impairment, sick leave, and in-patient hospitalization); concomitant medication

Data sources: Case report form (CRF)

Results: Adalimumab treatment was associated with reductions in mean DAS28, tender and swollen joint counts, and extent and severity of psoriasis throughout 24 months in patients who continued on therapy. Additional disease activity parameters, including the presence of enthesitis, dactylitis, and nail psoriasis, erythrocyte sedimentation rate (an inflammatory marker), and patient-reported outcomes, including function and pain, also improved during therapy. Reductions were observed in days of impairment, sick leave, and hospitalization. Positive predictors of improvements in DAS28 at month 6 included higher baseline DAS28, male gender, and higher functional status at baseline. Male gender was also the strongest predictor of improvements in function at month 6. In the safety set, drug-related AEs were reported in 18.9% of patients and serious AEs in 3.1%. One death due to a cardiac event was reported during the study. AE reports were consistent with the known adalimumab safety profile and no unexpected AEs were observed.
Discussion: Data at 24 months were available for 1531 (43.1%) subjects in the FAS; 25.4% discontinued and 31.5% were lost to follow-up. Adalimumab showed consistent and sustained effectiveness throughout 24 months, although continued improvements at later time points may have been influenced by responder bias. The findings of this non-interventional study support the conclusion that adalimumab is effective and safe during long-term therapy of adult PsA patients in Germany.
Marketing Authorization Holder: AbbVie Ltd.
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